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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/816,769	04/01/2004	Arnold C. Takemoto	ATAKEM-005-USA	2794

7590 02/23/2007

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EXAMINER	
VAKILI, ZOHREH	
ART UNIT	PAPER NUMBER
1614	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/23/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/816,769	TAKEMOTO, ARNOLD C.	
	Examiner	Art Unit	
	Zohreh Vakili	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Claims

Claim 1 is presented for examination.

Oath/Declaration

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because: The title submitted on the oath is not consistent with the specification. Specifically, the oath says "Detoxification and breast health kits" and the specification says "Detoxification and breast health preparations". The titles should be all consistent throughout the application.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Santamaria et al. (Patent No. 6800473 B1) in view of Safe (US PUB No. 2002/0115708 A1) and further in view of Howard et al. (Patent No. 6099854) taken with Bucci (Patent No. 6117429) and Morris (US Pub. No. 2002/0128239 A1).

Santamaria et al. teach a novel protein which belong to the papain family and are cysteine proteinase enzymes which play important roles in a variety of pathological conditions such as Alzheimer's disease, pulmonary emphysema, cancer invasion and metastasis (see abstract). The culture medium may contain carbon sources, nitrogen sources, minerals, etc. Examples of the minerals may include calcium chloride, magnesium chloride, etc. (see column 25, lines 17-26). Attached moieties include polycationic moieties such as polylysine that act as charge neutralizers of the phosphate backbone, or hydrophobicmoieties such as lipids, for example, phospholipids, cholesterols, etc. that enhance interaction with cell membranes or increase uptake of the nucleic acid (see column 34, lines 65-67 & column 35, lines 1-3). Those that are capable of forming a thiol compound such as lipoic acid or glutathione by utilizing the action of enzymes (see column 41, lines 60-65). The chelating agent is more preferably ethylenediamine tetraacetate (EDTA) (see column 43, line 21-22).

Safe discloses methods and compositions for the treatment of a wide array of cancers and tumors. Diindolylmethanes, C-substituted diindolylmethanes, and analogs thereof when administered either alone, or in combination with other anti-cancer or anti-tumorigenic compounds, provide new therapies for the treatment of cancer (see abstract).

Howard et al. teach a flavonol-containing dry composition derived from wine and useful as a food supplement is provided wherin at least 25% of the composition derived from the wine includes polyphenols (see abstract). It is recognized that many diseases are caused or provoked by a free radical oxidation mechanism, for example, cancer. Antioxidant nutrients such as vitamin E, vitamin C and others are though to prvent free radical oxidation in many organs and tissues. Thus the absorption of polyphenols which are effective antioxidants are likely to have an effect on free radical/oxidation diseases in general (see column 3, lines 62-67 & column 4, lines 1-3). The compositions conveniently comprise polyphenols (including flavonols) obtained from grapes (whole grapes or parts thereof, such as skins or juice (see column 6, lines 52-55). 50 mgs/day anthocyanins as grape skin extract given as a drink to a group test substance (see column 11, lines 52-53).

Bucci teaches that estradiol and dihydrotestosterone enhance or cause hormone-responsive illnesses such as breast or prostatic cancer (see abstract). Natural products containing anti-estrogen activity---the natural products with an anti-estrogen activity reduce or inhibit estrogen effects in estrogen-responsive tisssues. Estrogen-responsive tissues include liver, adipose, prostate, ovarian, uterine, and breast tissues (see column 4, lines 60-67). The natural products may include, catechin polyphenols, tocotrienols, isoflavones, indoles, saponins and glucarates. Bucci further teaches that catechin polyphenols, bioflavonoids, indoles and saponins in green tea, soy and other plants are effective in blocking estrogen receptors in prostate tissue. Glucarates, tocotrienols and indole-3-carbinol stimulate the removal of estrogen from the body (see

column 5, lines 1-9). Bucci disclose the preferred glucarates are calcium-D-glucarate, potassium hydrogen D-glucarate, glucaric acid and pharmaceutically-acceptable salts (see column 5, lines 29-31).

Morris teach a pharmaceutical composition suitable for the treatment of cancer and in particular with a pharmaceutical composition containing vitamin D, analogue or metabolite and the use of these compositions in the treatment of a tumor in a subject (see abstract). Morris further teach the vitamin D is dissolved in a lipid (page 1, paragraph 7) that preferably the lipid used is one for which the tumor is avid so that high concentrations of the vitamin D compound are delivered to the tumor (see page 1, paragraph 11). The pharmaceutically acceptable lipid may be an oil. The oil may be derived from shark liver oil. The lipid may be medium chain triglycerides (see page 1, paragraph 12). The lipid may be in the form of an emulsion of these oils prepared with pharmaceutically acceptable emulsifying agents including natural and synthetic phospholipids, Spans, or Tweens (see page 1, paragraph 14).

It would have been obvious given the motivation above to one of ordinary skill in the art, to have combined the teachings of Santamaria et al., Safe, Howard et al., Bucci and Morris for the reasons cited above. All references teach the treatment of breast cancer. Each component of the composition and its usage is taught in the references. As combined, the cited references result in the claimed invention.

One skilled in the art would have been motivated to combine the teachings of the above references considering that it is generally prima facie obvious to combine two or more compositions each of which is taught by the prior art to be useful for the same

purpose, in order to form a composition which is to be used for the very same purpose. The idea for combining them flows logically from their having been used individually in the prior art. As shown by the recited teachings, the instant claims define nothing more than the concomitant use of many anti-cancer agents. It would follow that the recited claims define prima facie obvious subject matter. In re Kerhoven, 626 F.2d 848, 205 USPQ 1069 (CCPA 1980).

Thus the claimed invention was within the ordinary skill in the art to make and use at the time the claimed invention was made and as a whole, prima facie obvious.

The examiner acknowledges that the preamble recites a kit. The kit essentially implies a packaging, which is an intended use of the claimed components.

If the body of a claim fully and intrinsically sets forth all of the limitations of the claimed invention, and the preamble merely states, for example, the purpose or intended use of the invention, rather than any distinct definition of any of the claimed invention's limitations, then the preamble is not considered a limitation and is of no significance to claim construction. See *Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1305, 51 USPQ2d 1161, 1165 (Fed. Cir. 1999). See also *Rowe v. Dror*, 112 F.3d 473, 478, 42 USPQ2d 1550, 1554 and MPEP §2112.02(II).

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zohreh Vakili whose telephone number is 571-272-3099. The examiner can normally be reached on 8:30-5:00 Mon.-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached at 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Zohreh Vakili
Patent Examiner
1614

February 16, 2007

Ardin H. Marschel 2/20/07
ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER

ZV 12 FEB 07